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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,663	06/25/2003	Pierre Charneau	03495.0199-01	8007

22852 7590 05/30/2007  
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EXAMINER
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HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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05/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,663	<b>Applicant(s)</b> CHARNEAU ET AL.	
	<b>Examiner</b> Louise Humphrey, Ph.D.	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 41-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 March 2007 has been entered.

**DETAILED ACTION**

Claims 41-51 are pending and examined.

The nonstatutory double patenting rejection of claims 41-51 as being unpatentable over claims 1-4, 8-11, 14, 15, 22 and 23 of US Patent No. 6,682,907 is maintained until the terminal disclaimer filed on 13 July 2006 is granted. Likewise, the provisional nonstatutory obviousness-type double patenting rejection of claims 41-45 and 51 as being unpatentable over claims 36, 40, 43, 44 and 69 of copending Application No. 10/313,038 is maintained until the terminal disclaimer filed on 13 July 2006 is granted.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 41-51 under 35 U.S.C. §102(b) as being anticipated by Verma *et al.* (WO 97/12622) is withdrawn in view of Applicants' argument, on page 6 of the response filed on 09 March 2007, that the transfer vector taught by Verma *et al.* does not comprise a retroviral *pol* sequence or cPPT or CTS, as illustrated in Figure 1.

The rejection of claims 41-48, 50 and 51 under 35 U.S.C. §102(b) as being anticipated by Parolin *et al.* (1994) is withdrawn in view of Applicants' argument that Parolin teaches a truncated *pol* sequence that does not include the cPPT and CTS sequences.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41-51 are rejected under 35 U.S.C. §103(a) as being unpatentable over Verma *et al.* (WO97/12622, in IDS) in view of Charneau *et al.* (1994, in IDS, Charneau'94) and Charneau *et al.* (1992, in IDS, Charneau'92).

The amended claims are directed to a recombinant transfer vector, comprising: a polynucleotide comprising a cis-acting central initiation region, which is the central polypurine tract ("cPPT"), and a cis-acting termination region, which is the central terminator sequence ("CTS"), wherein the cPPT and CTS are of the central polypurine tract ("cPPT") retroviral-like origin and derived from a retrotransposon and which form a triple-stranded sequence (DNA triplex); a defined nucleotide sequence (transgene or sequence of interest); and regulatory signals for reverse transcription, expression, and packaging, wherein said regulatory signals are of retroviral or retroviral-like origin; and wherein said transfer vector transfers the defined nucleotide sequence into the nucleus of a cell.

Verma *et al.* disclose a recombinant transfer vector comprising a transgene, encoding for luciferase or  $\beta$ -galactosidase, HIV-1 LTR and RRE, a packaging construct comprising HIV Gag, Pol, Vif, Tat, Rev and Nef, and a pseudotyping MLV vector comprising HIV Env. See Figure 1. The Verma transfer vector does not comprise cPPT and CTS.

However, Charneau'94 disclose that cPPT is an important cis-acting sequence for infectivity. See page 651, right column, last ¶. Charneau *et al.* further disclose a cis-acting CTS that is essential for HIV replication. See page 652, left column, 2<sup>nd</sup> ¶. Charneau *et al.* specifically disclose the nucleotide sequence of CTS. See page 654, Figure 2. Charneau'94 does not disclose the nucleotide sequence of cPPT.

Charneau'92 disclose the nucleotide sequence of cPPT. See page 2815, Figure 1(a).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Verma vector so as to include the cPPT and CTS as taught by Charneau'92 and Charneau'94. The skilled artisan would have been motivated to do so to improve the replication of the viral vector inside a cell and enhance the level of expression of the heterologous gene. There would have been a reasonable expectation of success, given the routine practice of molecular cloning in the art and the importance of cPPT and CTS for HIV replication, as taught by the two Charneau references. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

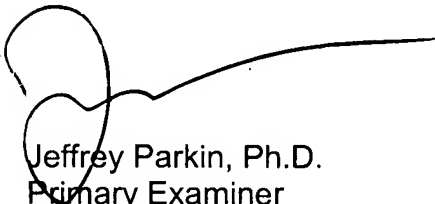
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**Correspondence**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.  
Primary Examiner  
17 May 2007



Louise Humphrey, Ph.D.  
Assistant Examiner